REMARKS

Applicants are amending their claims by adding new claim 21 to the application. Claim 21, dependent on claim 1, recites that the acetic anhydride is employed as a dehydrating agent for water generated in the reaction step. Note, for example, the second full paragraph on page 10 of Applicants' specification.

It is respectfully submitted that all of the presently pending claims patentably distinguish over the teachings of the references applied by the Examiner in rejecting claims in the Office Action dated January 5, 2009, that is, the teachings of U.S. Patent No. 5,892,138 to Singh, et al., Japanese Patent Document No. 2003-89673 (Aizawa, et al.), and Japanese Patent Document No. 2003-012597 (Igari, et al.), under the provisions of 35 USC 103.

It is respectfully submitted that the references as applied by the Examiner would have neither taught nor would have suggested such a process for producing 5-iodo-2-methylbenzoic acid as in the present claims, including, inter alia, wherein the reaction step of iodinating 2-methylbenzoic acid is performed in the presence of (1) H-β-form zeolite, the H-β-form zeolite having an Si/Al mole ratio of 10 to 250, (2) acetic anhydride in addition to acetic acid, (3) iodine, and (4) at least one of iodic acid and periodic acid. See claim 1.

It is emphasized that according to the invention as presently claimed, the reaction step of iodinating 2-methylbenzoic acid is performed in the presence of, inter alia, both acetic anhydride and acetic acid. The acetic anhydride acts as a dehydrating agent; see especially claim 21. As seen in the Examples and Comparative Examples of the above-identified application, and as discussed further infra, if materials recited in the present claims (e.g., if the acetic anhydride) were not used, both the yield and selectivity of 5-iodo-2-methylbenzoic acid, and the purity in

crystals, are reduced together. And if the acetic anhydride and acetic acid are not used, iodine content in the crystals is greatly increased because of a reduction of conversion of iodine. The remaining iodine causes an increase in the load of separation/recovery during the purification step.

Using both acetic acid and acetic anhydride together gives not only a very high selectivity, yield and purity, but also very small iodine content in the crystals, which would have neither been disclosed nor suggested by the applied references, discussed infra.

In addition, it is respectfully submitted that these references as applied by the Examiner would have neither taught nor would have suggested such a process for producing 5-iodo-2-methylbenzoic acid as discussed previously, having features as discussed in connection with claim 1, and, additionally, wherein the H-β-form zeolite is subjected to calcining after separating and recovering the H-β-form zeolite from a reaction mixture resulting from the reaction step. See claim 8, and claims dependent thereon. Calcining of the H-β-form zeolite results in prolonging the life of the catalyst, as can be seen in Examples 9-11 on pages 27 and 28 of Applicants' specification, including Tables 3-5, respectively.

Furthermore, it is respectfully submitted that the teachings of the applied references would have neither disclosed nor would have suggested such a process for producing 5-iodo-2-methylbenzoic acid as in the present claims, having features as discussed previously in connection with claim 1, and further including, inter alia (but not limited to), wherein the H-β-form zeolite contains an element other than Si, Al, and O, which form a skeleton thereof, within or outside the skeleton (see claim 4), in particular wherein this element other than Si, Al and O is at least one member selected from among those set forth in claim 5; and/or wherein the H-β-form zeolite

is separated and recovered from a reaction mixture resulting from the reaction step, followed by re-employment in the reaction step (see claim 7), particularly wherein the separated and recovered H-β-form zeolite is washed with acetic acid serving as the solvent (see claim 10); and/or wherein the purification step is a crystallization step in which a product is precipitated through cooling or addition of water (see claim 13), more particularly, further definition of the purification as in claims 14, 15 and 19.

In addition, and as will be discussed further infra, it is respectfully submitted that the evidence of record, that is, the evidence in the Examples and Comparative Examples in Applicants' specification, as well as the presently submitted Declaration establishes unexpectedly better results achieved by the present invention, wherein the reaction step of iodinating 2-methylbenzoic acid is performed in the presence of (1) H-β-form zeolite, (2) both acetic acid and acetic anhydride, (3) iodine, and (4) at least one of iodic acid and periodic acid, as compared with processes of the closest prior art and/or processes even closer than the closest prior art, and based thereon overcomes any possible prima facie case of obviousness established by the teachings of the applied references and clearly supports a conclusion of unobviousness of the present invention. In this regard, it is respectfully submitted that the experimental data in Applicants' specification must be considered in determining obviousness. See In re DeBlauwe, 222 USPQ 191 (CAFC 1984).

In particular, attention is respectfully directed to the enclosed Declaration. This Declaration includes Comparative Example 2'. Comparative Example 2' uses the same apparatus as employed in Example 1 of Applicants' specification, starting from page 18 thereof, and uses the same amount of acetic acid, 2-methylbenzoic acid, iodine and the 70% aqueous iodic acid solution as used in this Example 1. Comparative Example 2' differs from Example 1 in Applicants' specification, in using

concentrated sulfuric acid as a catalyst, consistent with the disclosure in Igari, et al., and in omitting acetic anhydride. Attention is respectfully directed to the results on page 2 of this Declaration, including a yield of 5-iodo-2-methylbenzoic acid of 69.2%, with 74.6% selectivity; and a purity in crystals of 5-iodo-2-methylbenzoic acid of 85.3%. Compare with the results in Example 1 in Applicants' disclosure, having a 92.0% yield of 5-iodo-2-methylbenzoic acid, and a purity in crystals of 5-iodo-2-methylbenzoic acid of 99.7%. Clearly, results in Example 1 in Applicants' original specification, which is evidence to be considered, are unexpectedly better than the results in Comparative Example 2' in the enclosed Declaration. It is respectfully submitted that this evidence shows unexpectedly better results achieved by the present invention, utilizing, inter alia, acetic anhydride and H-β-form zeolite, establishing unobviousness of the presently claimed subject matter even were the teachings of the applied references to establish a prima facie case of obviousness (which, as will be shown infra, Applicants respectfully submit that the teachings of the applied references do not establish such prima facie case).

The comments by the Examiner in the paragraph bridging pages 4 and 5 of the Office Action mailed April 4, 2008, in the above-identified application, are noted. Therein, the Examiner contended that the evidence of record at such time did not provide side-by-side comparisons with the prior art, the Examiner contending that Applicants failed to provide a true side-by-side comparison that clearly demonstrates which reagents must necessarily be present and is responsible for the allegedly high yields, purities and selectivity, the Examiner pointing to Example 1 on page 18 and Comparative Example 2 on page 22 as using different amounts of reagents, so it is unclear how the final purity and yield are achieved. In contrast, Example 1 in Applicants' specification and the enclosed Comparative Example 2' use the same

reagents and amounts, except for omission of the acetic anhydride in Comparative Example 2' and substitution of concentrated sulfuric acid for H-β-form zeolite in Comparative Example 2'. Note that same amounts of concentrated sulfuric acid and of H- β-form zeolite were used respectively in Comparative Example 2' and Example 1. It is respectfully submitted that even under the standards as required by the Examiner, Example 1 of Applicants' specification and the enclosed Comparative Example 2' provide a fair comparison, and establish unexpectedly better results in purity and yield of 5-iodo-2-methylbenzoic acid achieved by the present invention.

The present invention is directed to a process for producing 5-iodo-2-methylbenzoic acid, and to high-purity 5-iodo-2-methylbenzoic acid produced by such process.

As described on pages 1-5 of Applicants' specification, there have been known methods for synthesizing 5-iodo-2-methylbenzoic acid. However, these various known methods have problems. For example, various of the methods have a low yield and/or low selectivity and/or produce a low purity product, e.g., producing relatively large amounts of 3-iodo-2-methylbenzoic acid rather than 5-iodo-2-methylbenzoic acid. In addition, other methods utilize highly toxic materials, making such techniques inappropriate for an industrial scale, or require complex processing, or require materials (e.g., sulfuric acid) which need burdensome treatment, and/or have high processing costs. It is desired to provide a high-efficiency industrial process for producing 5-iodo-2-methylbenzoic acid through iodination of 2-methylbenzoic acid as starting material, which is a relatively simple production process and is able to product a high-purity product with high selectivity for the desired product, and provides the desired product at high yield.

Against this background, Applicants have found that iodination of 2-methylbenzoic acid serving as a starting material can be performed at high selectivity through iodinating 2-methylbenzoic acid in the presence of (1) H-β-form zeolite, and (2) both acetic anhydride and acetic acid, in addition to (3) iodine and (4) at least one of iodic acid and periodic acid, and that a high-purity product can be achieved at high yield and high efficiency by combining the reaction step with a purification step including sublimation, distillation and/or crystallization. Note the first full paragraph on page 6 of Applicants' specification. Note also the paragraph bridging pages 36 and 37 of Applicants' specification.

It is emphasized that the reaction in the presently claimed process is conducted in the presence of, inter alia, (1) H-β-form zeolite and (2) both acetic anhydride and acetic acid. It is respectfully submitted that the results of the present invention are achieved by using all of the materials as in the present claim 1, as seen in the Examples and Comparative Examples in Applicants' original disclosure.

In addition to the previously discussed comparison of Example 1 in Applicants' specification and Comparative Example 2' of the enclosed Declaration, compare Example 1 and Comparative Example 4 respectively on pages 18 and 19, and on page 24, of Applicants' specification. It is respectfully submitted that this shows unexpectedly better results in yield and selectivity of 5-iodo-2-methylbenzoic acid, and purity in the crystals, achieved utilizing both acetic anhydride and acetic acid. Similarly, note Example 12 on pages 28 and 29, and Comparative Example 7 on pages 33 and 34, of Applicants' specification, again showing that when both acetic anhydride and acetic acid are used, yield and selectivity of the desired product, and purity in the produced crystal, were unexpectedly improved.

It is respectfully submitted that this evidence in Applicants' specification shows unexpectedly better results achieved by the presently claimed subject matter, overcoming any possible prima facie case of obviousness proposed by the Examiner, even assuming, arguendo, that the teachings of the applied references would have established a prima facie case of obviousness.

Attention is also directed to Examples 1, 3, 4, 12 and 14, on pages 18-21 and 28-31 of Applicants specification, as compared with Comparative Examples 5 and 7 on pages 31-34 of Applicants' specification. The Examples 1, 3, 4, 12 and 14 include acetic anhydride, whereas the Comparative Examples 5 and 7 do not. Note, especially, the comparison between Example 12 and Comparative Example 7, the difference therebetween being that in Comparative Example 7 acetic anhydride was not employed. It is respectfully submitted that these Examples and Comparative Examples show that by the present invention, wherein the reaction takes place in the presence of both acetic acid and acetic anhydride, an unexpectedly large conversion of iodine is achieved, whereby iodine content in the crystals is unexpectedly and advantageously decreased, avoiding the need for separation and recovery of an unduly large amount of remaining iodine in the purification step. It is respectfully submitted that this evidence of unexpectedly reduced amount of iodine shows further unexpectedly better results achieved according to the present invention, further supporting a conclusion of unobviousness of the presently claimed subject matter.

Attention is also respectfully directed to Example 1 on pages 18 and 19 of Applicants' specification, together with Examples 2 and 3 on pages 19-21 thereof. Note also Comparative Example 1 on pages 21 and 22 of Applicants' specification, using a reaction mixture including sulfuric acid (compare with the process in Japanese Patent Document No. 2003-012597, wherein 2-methylbenzoic acid was

reacted with iodine and periodic acid in the presence of sulfuric acid in AcOH). Note also Comparative Example 2, and Comparative Example 2' in the enclosed Declaration, also including sulfuric acid in the reaction mixture. Note that in Comparative Example 3, the procedure of Example 1 was repeated, except that iodic acid was not employed. As can be appreciated from disclosures on pages 21-24 of Applicants' specification, unsatisfactory results were achieved in each of the Comparative Examples 1-3.

See also the other Examples and Comparative Examples in Applicants' specification; in this regard, note Comparative Example 5 on pages 31 and 32, which shows that when concentrated sulfuric acid was employed as an acid catalyst, purity and yield of 5-iodo-2-methylbenzoic acid were unsatisfactory; and Comparative Example 6 on pages 32 and 33, disclosing that when sulfuric acid was employed as an acid catalyst, the formed 5-iodo-2-methylbenzoic acid crystals had a high iodine content, so that high-purity 5-iodo-2-methyylbenzoic acid was not produced.

As can be seen from the foregoing, as well as from a full review of the Examples and Comparative Examples in Applicants' specification, and the Comparative Example 2' in the enclosed Declaration, it can be seen that by conducting the iodination reaction in the presence (1) the H-β-form zeolite, (2) iodine, (3) iodic acid and/or periodic acid and (4) both acetic anhydride and acetic acid, unexpectedly better results in selectivity and yield, as well as high purity, are achieved. It is respectfully submitted that the advantageous results achieved by the present invention would have been unexpected, and it is respectfully submitted that the unexpectedly better results achieved according to the present invention support a conclusion of unobviousness thereof.

Igari, et al. discloses a method for producing monoiodo compounds of methylbenzoate, wherein such compounds are produced by directly iodizing methylbenzoate, a raw material, by using an iodizing agent together with an acid catalyst in a solvent. Specifically, this patent document discloses reacting 2-methylbenzoic acid with iodine and periodic acid in the presence of H_2SO_4 in AcOH. Note the English Abstract of Igari, et al., as well as paragraphs [0001], [0006] and [0010] of the machine generated English translation thereof enclosed with the Office Action mailed April 4, 2008.

Aizawa, et al. discloses a method for separating and purifying an isomer mixture of iodo-2-methylbenzoic acid, the method changing the iodo-2-methylbenzoic acid mixture comprising 3-iodo-2-methylbenzoic acid and 5-iodo-2-methylbenzoic acid to corresponding metal salts, adjusting the pH of the aqueous solution of the metal salts to 5.0 ± 0.5 at normal temperatures, and separating precipitating crystals as 5-iodo-2-methylbenzoic acid as a principal compound by filtration, and separating the 3-iodo-2-methylbenzoic acid as a principal compound by adjusting the pH of the filtrate to 3.0-2.0 by addition of an acid. Note the English abstract of Aizawa, et al., as well as paragraphs [0001], [0007] and [0016] of the machine-generated English translation thereof enclosed with the Office Action mailed April 4, 2008.

Singh, et al. discloses a process for the preparation of halocumenes. The process includes reacting cumene with a halogenating agent in a liquid phase in the presence of an aliphatic carboxylic acid and a specified microporous zeolite catalyst. Note column 2, lines 19-32. See also column 2, lines 49-56.

Initially, it is respectfully submitted that the teachings of Singh, et al. would not have been properly combinable with the teachings of the two applied Japanese

patent documents. Thus, each of the two applied Japanese patent documents is directed to providing iodo compounds of methylbenzoic acid or an ester thereof. In contrast, Singh, et al. is directed to preparation of 4-halocumenes. In view of different technologies involved in the two Japanese patent documents, on the one hand, and in Singh, et al., on the other, and in view of different problems addressed by each, it is respectfully submitted that one of ordinary skill in the art concerned with in the two Japanese patent documents would not have looked to the teachings of Singh, et al.

Furthermore, in view of the different technologies, as well as different problems addressed by the applied references, as discussed previously, it is respectfully submitted that there would have been no reason to combine the teachings of the applied references, as combined by the Examiner, absent hindsight use of Applicants' disclosure, which of course is improper under the requirements of 35 USC 103.

In any event, even assuming, arguendo, that the teachings of the three references applied by the Examiner were properly combinable, such combined teachings would have neither disclosed nor would have suggested the presently claimed process, including wherein the reaction takes place in the presence of all of H-β-form acetic acid, iodine, periodic acid and/or iodic acid, and both acetic anhydride and acetic acid.

Furthermore, even were the teachings of Singh, et al. to be properly combinable with the teachings of the two Japanese patent documents, e.g., even were a microporous compound of Singh, et al. used in exchange for sulfuric acid in the process of Igari, et al., the yield is 60.2% and the yield of crystals is 45.8%. Note Comparative Example 4 on page 24 of Applicants' specification. Clearly, substitution

of the microporous compound of Singh, et al. would not have provided the advantageous results achieved by the present invention.

It is emphasized that according to the present invention, the advantageous results are achieved utilizing each and every one of the features recited in the present claims, including (1) the H-β-form zeolite having an Si/Al mole ratio of 10-250, (2) both acetic anhydride and acetic acid, (3) iodine, and (4) at least one of iodic acid and periodic acid. The advantageous effects achieved according to the present invention, utilizing each and every one of the foregoing features, would not have been disclosed, nor would have suggested, by the teachings of the applied references.

The contention by the Examiner on page 4 of the Office Action mailed January 5, 2009, that the claims would have been obvious "because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner", is noted. The Examiner does not set forth what design incentives, or what market forces, provide a reason to make an adaptation. Moreover, as shown by the evidence of record, the results were not predictable. Clearly, the conclusion by the Examiner, without any evidence or reasoning in support thereof, is improper under the requirements of 35 USC 103. Note In re McKellin, 188 USPQ 428 (CCPA 1976).

The further contention by the Examiner on page 4 of the Office Action mailed January 5, 2009, that one skilled in the art "could have combined the elements as claimed", is noted. Even assuming, arguendo, that the Examiner were correct that the elements could have been combined (and, as seen in the foregoing, Applicants respectfully traverse the contention by the Examiner that such elements could have been combined), it is respectfully submitted that there must be a reason for

combining elements, in order to satisfy requirements of 35 USC 103, and that the conclusion that elements "could have been combined" does not provide a basis for a conclusion of obviousness under 35 USC 103.

The contention by the Examiner on page 4 of the Office Action mailed January 5, 2009, that the combination "would have yielded predictable results" is respectfully traversed, as seen in the evidence of record in the present application, and discussed previously.

The contention by the Examiner in the last paragraph on page 4 of the Office Action mailed January 5, 2009, is not understood. If the actual application of a technique "would have been beyond the skill of one of ordinary skill in the art", then the resulting subject matter would not have been obvious. Clearly, if the actual application of a technique would have been beyond the skill of one of ordinary skill in the art, then the "subject matter" would have been unobviousness "because one of ordinary skill in the art could not have been expected to achieve it".

Applicants note the provisional obviousness-type double patenting rejection set forth in Item 9 on pages 6 and 7 of the Office Action mailed January 5, 2009. As the claims of the above-identified application and of Application No. 10/545,005 are still in procedures of amendment, it is respectfully submitted that this provisional rejection should be held in abeyance until there are claims of some certainty in at least one of the applications. In this regard, note that claims in No. 10/545,005 have been amended since the rejection thereover in the Office Action mailed January 5, 2009.

In this regard, it is respectfully submitted that the Examiner has not established overlap between the present claims in No. 10/545,005, and the claims of the above-identified application. The general allegation of overlap, and the general

contention that "similar reactants and conditions" are set forth, does not establish a basis for a conclusion of obviousness-type double patenting.

In view of the foregoing comments and amendments, and also in view of the presently submitted Declaration, reconsideration of all claims being considered on the merits in the above-identified application, and indication of allowance thereof at least over the applied prior art, are respectfully requested.

Applicants request any shortage of fees due in connection with the filing of this paper be charged to the Deposit Account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (case 396.45629X00), and please credit any excess fees to such Deposit Account.

Respectfully submitted,

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